PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

4

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
99-0216		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/07739	09/08/2000	09/09/1999

International Patent Classification (IPC) or national classification and IPC
A61M25/01

Applicant
SCHNEIDER (EUROPE) GMBH et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12/02/2001	28.11.2001

Name and mailing address of the international preliminary examining authority:

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NL-2280 HV Rijswijk - Pays Bas
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/07739

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-6 as originally filed

Claims, No.:

1-18 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	17
	No:	Claims	1-16,18
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-18
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject matter of claims 1 to 16 and 18 lacks novelty over the contents of the documents cited as prior art in the international Search Report.

The wording of present claim 1 is particularly general referring to a "guiding aid" comprising a "flexible" and "shapeable" shaft having at least two bend sections. The feature "guiding aid" imposes no clear restriction on the device and while on the one hand, "flexible" is understood to encompass virtually everything up to rigid needle or trocar, "shapeable" is understood in the light of the description on page 2, line 29, to mean "industrially pre-formable" and is not therefore intended to refer to the device being malleable in the hands of the surgeon prior to insertion (according to the normal understanding of "shapeable", see also Item VII below). As such, all of the documents cited in the ISA-report are considered prejudicial to the novelty of the subject-matter of claim 1.

Document US-A-5639276 (henceforth D1) discloses (see col. 9, lines 8 to 65 , and figures 6a, 6b) a steerable guidewire which may be used as a guiding aid for a catheter 20. As such D1 discloses a guiding aid for an instrument to be advanced within a vascular system comprising a flexible shapeable shaft 61 comprising a first bent section having a first curvature and at least one further bent section with said bent sections having the same sign of curvature and being located substantially in the same plain.

Additionally, the second curve is obtuse in the range of 135° and the curves are apparently circular arcs. The shaft 61 in fig. 6b is tapered (line 52) and is surrounded by a helical spring 65 having a rounded terminal element 69.

Consequently, D1 anticipates all the features of claims 1 to 5, 7 to 12, 16 and 18.

Document WO-A-9632980 (henceforth D2) additionally discloses the particular shape (see fig. 3) which is apparently envisaged for the present device according to fig. 4 and as claimed in claims 1 to 9. Thus, the subject-matter of these claims lacks novelty also over the content of this document.

Document US-A-5680873 (henceforth D3) additionally discloses (see col. 6, lies 24 to 31) a guiding aid which can be curved corresponding to figure 2b and which is made of Nitinol and may include radioopaque means. The subject-matter of claims 1 and 13 to 15 thus also lacks novelty over this document.

Document US-A-4854330 (henceforth D4) convincingly explains (see col. 6, line 58 to col. 7. line 4) the advantageous steering effect of the tip region which clearly includes two bent sections Q and R according to fig. 6.

No inventive step can be seen in the adaption of a guiding aid as known from the above mentioned documents D1 to D4 as a pressure sensing wire as known from document WO-A-9732518, cited in the present description.. Consequently, the subject-matter of claim 17 does not involve an inventive step.

Re Item VIII

Certain observations on the international application

The wording of claim 1 does not exclude the possibility of further curved sections of opposite curvature which is apparently in contradiction to the description on page 2, line 21. On this basis, certain documents (US-A-4925445 and EP-A-0381810) would anticipate the subject-matter of claim 1 as well.

The term "shapeable" in claim 1 suggests that the shaft is formable by the user into a particular shape which then is maintained during use. According to the description on page 2, line 29, the shaft is however industrially pre-formable so that there exists another contradiction between the description and claims.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
99-0216		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 00/ 07739	09/08/2000	09/09/1999
Applicant		
SCHNEIDER (EUROPE) GMBH et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 4

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]EP 00/07739

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 22797 A (CARDIOGENESIS CORP) 14 May 1999 (1999-05-14) the whole document ---	1-9,18
X	WO 96 32980 A (JACOBS CLEMENS JOSEPHUS) 24 October 1996 (1996-10-24) page 4, line 4 - line 39; figure 3 ---	1-9, 13-18
X	US 5 722 963 A (OCKULY JOHN DAVID ET AL) 3 March 1998 (1998-03-03) column 2, line 41 - line 52; figure 2 ---	1-3,9
A	US 4 925 445 A (SAKAMOTO HIDETOSHI ET AL) 15 May 1990 (1990-05-15) cited in the application the whole document --- -/--	1-18

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 December 2000	11/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Clarkson, P

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]EP 00/07739

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 381 810 A (ADVANCED CARDIOVASCULAR SYSTEM) 16 August 1990 (1990-08-16) the whole document	1-3, 10-18
X	US 4 854 330 A (EVANS III RUSSELL M ET AL) 8 August 1989 (1989-08-08) the whole document	1-3,9-18
X	US 5 639 276 A (WEINSTOCK BARRY S ET AL) 17 June 1997 (1997-06-17) column 9, line 21 - line 47; figure 6B	1-18
X	US 5 680 873 A (BERG TODD A ET AL) 28 October 1997 (1997-10-28) *figure 2b and the related description*	1-5,9, 10,18

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
EP 00/07739

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9922797	A	14-05-1999	EP 1027089	A	16-08-2000
WO 9632980	A	24-10-1996	NL 1000183	C	22-10-1996
			AU 707674	B	15-07-1999
			AU 5409396	A	07-11-1996
			CA 2218508	A	24-10-1996
			CN 1181710	A	13-05-1998
			EP 0821602	A	04-02-1998
			JP 11503633	T	30-03-1999
			US 6074361	A	13-06-2000
US 5722963	A	03-03-1998	US 5549581	A	27-08-1996
			US 5423772	A	13-06-1995
			US 6001085	A	14-12-1999
			US 5984909	A	16-11-1999
			US 5643231	A	01-07-1997
US 4925445	A	15-05-1990	JP 1652751	C	30-03-1992
			JP 2024549	B	29-05-1990
			JP 60063065	A	11-04-1985
			JP 1664876	C	19-05-1992
			JP 2024550	B	29-05-1990
			JP 60063066	A	11-04-1985
			AU 562843	B	18-06-1987
			AU 3249884	A	21-03-1985
			CA 1232814	A	16-02-1988
			DE 3477737	D	24-05-1989
			EP 0141006	A	15-05-1985
EP 0381810	A	16-08-1990	US 5007434	A	16-04-1991
			CA 1329095	A	03-05-1994
			DE 68918931	D	24-11-1994
			DE 68918931	T	11-05-1995
			JP 2215476	A	28-08-1990
			JP 3020514	B	15-03-2000
US 4854330	A	08-08-1989	NONE		
US 5639276	A	17-06-1997	NONE		
US 5680873	A	28-10-1997	CA 2214111	A	06-09-1996
			EP 0902703	A	24-03-1999
			JP 11500939	T	26-01-1999
			WO 9626758	A	06-09-1996

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/23276

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
DE 9215779	U	04-02-1993	NONE		
EP 0727236	A	21-08-1996	US	5722400 A	03-03-1998
			US	5833673 A	10-11-1998
			CA	2151019 A	17-08-1996
			CA	2153303 A	17-08-1996
			EP	0727237 A	21-08-1996
			JP	8266551 A	15-10-1996
			JP	8252262 A	01-10-1998
			US	5814029 A	29-09-1998
WO 9635469	A	14-11-1996	CA	2220689 A	14-11-1996
			EP	0892651 A	27-01-1999
WO 9630072	A	03-10-1996	AU	5188596 A	16-10-1996
			CA	2215970 A	03-10-1996
			EP	0819013 A	21-01-1998
EP 0728494	A	28-08-1996	AU	691999 B	28-05-1998
			AU	4034595 A	20-06-1996
			CA	2165255 A	16-06-1996
			JP	8215313 A	27-08-1996

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 March 2001 (15.03.2001)

PCT

(10) International Publication Number
WO 01/17601 A1

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(21) International Application Number: PCT/EP00/07739

(22) International Filing Date: 9 August 2000 (09.08.2000)

(25) Filing Language: English

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(30) Priority Data:
99117818.7 9 September 1999 (09.09.1999) EP

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(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SCHWAGER, Michael** [CH/CH]; Hegifeldstrasse 9, CH-8404 Winterthur (CH).

(74) Agents: SCHWAN, Ivo et al.; Schwan - Schawn - Schorer, Elfenstrasse 32, D-81739 München (DE).

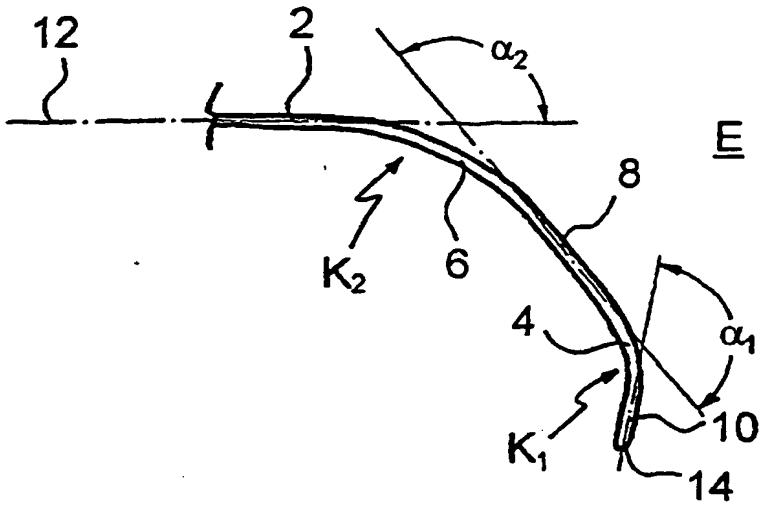
(81) Designated States *(national)*: CA, JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: GUIDING AID



(57) Abstract: A guiding aid for an instrument to be advanced within a vascular system, particularly the human vascular system, comprising a flexible shapeable shaft (2) comprising a first bent section (4) having a first curvature (K_1) and at least one further bent section (6), wherein said bent sections (4, 6) of said shaft (2) have the same sign of curvature and are located substantially within the same plain (E). Such a guiding aid may be pre-formed by the manufacturer such that the guiding aid may be introduced into vascular branchings both from large lumen and small lumen vessels by a physician manipulating the instrument from its proximal end.

WO 01/17601 A1

Guiding Aid

The invention relates to a guiding aid for an instrument to be advanced within a vascular system, particularly the human vascular system, comprising a flexible, formable shaft having a bent section with a predetermined curvature.

Such guiding aids are used in transluminal interventions in the human vascular system where elongated instruments such as guide wires or catheters are manipulated at their proximal end by a physician to advance those instruments along a certain path through the vascular system to a site of treatment. For this purpose the instrument comprises at its distal end a tip which has approximately J-shape and which either is pre-formed by the manufacturer or is individually bent by the physician. The column strength and the torsional strength of the instrument provide for axial and rotational movements being transferred from the proximal end of the instrument directly to the tip thereof. With the distal J-bow being correctly dimensioned the physician may navigate the instrument along a path selected by him through a branched vascular system such as the human blood vessel system.

From the prior art there are known various embodiments of instruments with such guiding aids. US-A-4 846 186 discloses a flexible guide wire for advancing diagnostic and therapeutical catheters. The tapered core wire is flattened at its distal end such that it may be bent by the treating physician in this area into J-shape. A further application is shown in European Patent 0 220 285 wherein a balloon catheter is provided with a fixedly installed guide wire. The shaft of the wire which protrudes beyond the balloon is tapered and is surrounded by a wire helix. In the distal end section there is attached to the wire a shaped element made of stainless steel which in the relaxed state has a pre-selected curvature to serve as guiding aid. A guiding aid of the type mentioned above further is known from WO 97/32518; here there is provided a guide wire having a pressure measurement feature. At the distal end of the tubular wire there are located lateral openings through which a pressure pulse of the blood may propagate through the lumen of the tubular element to a pressure sensor located at the proximal end. A tip made of a formable shaft and a wire helix surrounding the shaft are provided at the distal end of the tubular element. Once the tips of the aforementioned embodiments are pre-formed the shape of the tip may not be changed any further during use thereof.

A guide wire having a tip the shape of which may be changed is known from US-A-5 040 543. For this purpose the wire comprises an axially moveable core element the distal end of which may straighten the pre-curved helical wire tip. Thus the physician may control the size of the J-bow during the treatment from outside the patient. However, this construction is complicated and there is the risk, that the tip of the moveable core element may emerge between adjacent windings of the wire helix and may injure the inner wall of the vessel.

US-A-4 925 445 discloses a guide wire for a catheter having a comparably stiff main section and a comparably flexible distal end section. These sections are made at least in part of a super elastic member. In order to prevent that the tip of the distal end section penetrates the wall of the vessel the tip is R-shaped, ball-shaped, J-shaped, annular or spiral. In order to be able to insert the distal end section in a simple and safe manner to a pre-selected position within the blood vessel, the distal end section is pre-formed by a curvature that corresponds to the anatomy of the vascular system or the vascular branching. This is disadvantageous in that for each individual intervention an individual shape of the guide wire tip has to be pre-manufactured which requires extensive storage.

It is therefore an object of the invention to provide for a guiding aid of the above mentioned type that is simple in construction and safe in application and which may be used for guiding elongated instruments in branchings of both large and small vessel diameters. This object is attained by a guiding aid of the above mentioned type, the shaft of which comprises at least one further bent section, wherein all bent sections of the shaft exhibit the same sign of curvature and are located substantially in the same plain. In large vessels the shaft, by means of the plurality of sections being bent in the same direction, may provide for sufficient total curvature such that the guiding aid may be threaded into a branching, optionally by bearing against a wall of the vessel opposite the branching. When being used in small vessels the further bent sections of the shaft proximal the first bent section of the guiding aid are straightened while the distal first bent section, when the curvature thereof is suitably dimensioned, maintains its shape to be maneuvered into a branching. Thus there is provided for an industrially pre-formable and thus standardized guiding aid that is suited for being threaded into branchings both from large and from small vessels. Furthermore, the physician no longer has to pre-form the shaft prior to the intervention himself.

In a preferred embodiment of the invention the shaft comprises just one further or second bent section having a further or second curvature that is located proximal of the first bent section such that the advantages of the invention are attained in a particular simple way by requiring that only two bent sections have to be pre-formed.

In a preferred embodiment of the invention the radius of curvature of the first bent section is smaller than the radius of curvature of the second bent section. Thereby the risk for buckling of the proximal curvature is lowered and the proximal curvature thereby is better adapted to transfer an axial movement to the distal curvature and the tip.

Preferably the shaft comprises between the first bent section and the second bent section a straight intermediate section in order to provide for an intermediate section that is stable for the transfer of axial movements which for example assists in preventing the distal end section of the guiding aid from again leaving a branching already entered by the distal end section.

In an advantageous embodiment of the invention the shaft comprises a straight end section distal to the first bent section. This distal end section facilitates the entry into a branching by acting as support for the distal end of the shaft protruding into the branching.

In a preferred embodiment of the invention the straight end section and the straight intermediate section include a first obtuse angle and the straight intermediate section and the instrument axis include a second obtuse angle comprising an angle of in the range of from 120 to 150°, preferably of about 135°. As a result the straight end section is oriented laterally, for example under an angle in the order of about 90°, to the instrument axis in the direction of the opening of a branching and may be introduced into the branching particularly easy.

Advantageously the bent sections are substantially in the shape of a circular arc. This type of curvature is uniform and may be provided for with the most simple means.

In a further preferred embodiment of the invention the shaft is tapered towards its distal end, such that the shaft is more and more flexible towards its distal end. Thereby the risk of injury of the inner wall of the vessel by the tip of the shaft of the guiding aid is reduced.

In a further preferred embodiment of the invention there is provided around the shaft at least partially a helically wound spring. Thereby the risk for kinking of the wound shaft section is lowered while maintaining high flexibility. Furthermore, by means of the spring a rapid change of the outer diameter of the guiding aid is avoided in the tapered shaft. Preferably, the helically wound spring is provided at its distal end with a rounded terminal element to further lower the risk of injury.

In a further advantageous embodiment of the invention the shaft is comprised of a material with super elastic characteristics, preferably of super elastic Nitinol. Due to the shaft shape of the invention being adapted to be pre-shaped by the manufacturer this material having a shape memory effect may be used for the shaft.

In another preferred embodiment of the invention radiopaque means are provided in the region of the distal end of the shaft such that the instrument tip may be followed during navigation by the physician on an X-ray screen.

The invention relates further to the use of a guiding aid as described above with steerable instruments. In particular, the guiding aid of the invention may be located at the distal end for example of a guide wire, a pressure sensing wire or a balloon catheter. The practical attainment of the locating procedure or the attachment respectively of a guiding aid in or at such an instrument is known from the prior art described above such that these instruments may be provided with the inventive shape of the guiding aid and its advantageous use.

Further advantages of the guiding aid of the invention will become apparent from the description of a preferred embodiment which will be described below by reference to the attached drawings wherein:

FIG. 1 shows a guiding aid comprising a J-shaped tip having the correct dimensions for the branching conditions;

FIG. 2 illustrates a guiding aid with a J-shaped tip being dimensioned too large for the branching conditions;

FIG. 3 illustrates a guiding aid with a J-shaped tip being dimensioned too small for the branching conditions;

FIG. 4 is a schematic illustration of a guiding aid of the invention;

FIG. 5 shows the guiding aid of FIG. 4 at a branching from a large vessel;

FIG. 6 shows the guiding aid of FIG. 4 at a branching from a small vessel; and

FIG. 7 shows a guide wire comprising a guiding aid of the invention in sectional view.

A prior art guiding aid for an instrument to be advanced within the human vascular system having a flexible, shapeable shaft 2 comprising a first bent section 4 having a first curvature K_1 in J-shape is shown in FIGS. 1 to 3 in vascular branchings of different size. In FIG. 1 the curvature K_1 is dimensioned such that the distance of the distal end 14 of shaft 2 from the instrument axis 12 corresponds to about the diameter of the vessel from which the guiding aid is to be threaded into a branching. In this manner the tip of the guiding aid may protrude into the branching vessel even when the guiding aid bears proximally to the bent section 4 against the wall of the vessel opposite to the opening of the branching vessel. By rotating the instrument and thereby rotating the guiding aid about the instrument axis 12 the distal end 14 thereof is introduced into the branching easily and rapidly, provided the dimension of the bent section 4 corresponds to about the vessel diameter.

In FIG. 2 the curvature K_1 is dimensioned such that the distance of the distal end 14 from the instrument axis 12 is substantially larger than the diameter of the vessel from which the guiding aid is to be introduced into a branching. Within the small vessel the bent section 4 of the guiding aid is straightened such that the tip is directed substantially in the direction of the instrument axis 12. Therefore the tip of the guiding aid tends to pass the opening of the branching which renders the threading thereof into the branching difficult.

Threading of the guiding aid into a branching is similarly difficult in case that, as is shown in FIG. 3, the curvature K_1 is dimensioned such that the distance of the distal end 14 from the instrument axis 12 is substantially smaller than the diameter of the main vessel. Within the large lumen vessel there is no suitable lateral support for the guiding aid because when the shaft 2 bears against the wall of the vessel the distal end 14 of the guiding aid does not protrude into the vessel opening. This demonstrates to what an extent the successful advancement of an instrument with guiding aid is determined by the dimensioning of the curvature K_1 in relation to the size of the vessel diameter.

The guiding aid of the invention shown in FIG. 4 comprises a flexible shapeable shaft 2 having a first bent section 4 with a first curvature K_1 and proximal thereto a second bent section 6 with a second curvature K_2, wherein the two bent sections 4 and 6 of the shaft 2 exhibit the same sign of curvature and are positioned substantially in the same plain E which in FIG. 4 is the drawing plain. Shaft 2 comprises a straight intermediate section 8 between the bent sections 4 and 6 and a straight end section 10 distal to the first bent section 4 which end section 10 constitues with its distal end 14 the tip of shaft 2. The straight intermediate section 8 and the axis 12 of the instrument include a first obtuse angle α_1 and the intermediate section 8 and the straight end section 10 include a second obtuse angle α_2. Bent sections 4 and 6 are substantially in the shape of a circular arc, with the radius of curvature of the first bent section 4 being smaller than the radius of curvature of the second bent section 6.

In FIGS. 5 and 6 there is shown how the guiding aid of the invention is threaded from a large vessel and from a small vessel, respectively, into a branching. As is shown in FIG. 5 the curvatures K_1 and K_2 of the two bent sections 4 and 6, respectively, are dimensioned such that the tip 14 of the guiding aid protrudes into the opening of the branching even if the main vessel has a large lumen and even if shaft 2 bears against the wall of the main vessel opposite the opening of the branching. In case of a small lumen vessel, such as is shown in FIG. 6, although the proximal bent section 6 is straightened, the distal bent section 4 is dimensioned such that its curvature K_1 may be maintained and the tip 14 of the guiding aid may be introduced into the branching.

FIG. 7 shows a guide wire that is provided with a guiding aid of the invention. The flexible, shapeable shaft 2 of the guiding aid is constituted by the distal portion of the core wire of the guide wire, which, for coronary applications, has an outer diameter of typically about 0.35 mm. A first bent section 4 has a first curvature K_1, and proximal thereto a second bent section 6 has a second curvature K_2, with the two bent sections 4 and 6 being bent in the same direction with respect to the axis 12 of the instrument, i.e. with the same sign of curvature, and which are positioned substantially in the same plain E, which in FIG. 7 is the drawing plain. Between the bent sections 4 and 6 shaft 2 comprises a straight intermediate section 8 having a length of approximately 3 mm, and distal to the first bent section 4 shaft 2 comprises a straight end section 10 with a length of approximately 1.5 mm. The straight intermediate section 8 and the axis 12 of the instrument include a first obtuse angle α_1, and the straight intermediate section 8 and the straight end section 10 include a second obtuse angle α_2, with both obtuse angles having a value of about 135°. The bent sections 4 and 6 a formed substantially in the shape of a circular arc, with the radius of curvature of the first bent section 4 being about 8 mm and the radius of curvature of the second bent section 6 being about 3 mm. Shaft 2 is tapered towards its distal end 14 via a plurality of conical intermediate sections. In order to provide for a substantially constant outer diameter of the guide wire, a helical spring 16 is wound at least partially around shaft 2, preferably within the tapered shaft portion which within the region of the distal end 14 of shaft 2 is made of an radiopaque material 20 which is threadedly connected to the proximal spring 16 at an attachment side 22 and/or is brazed or welded thereto. At the distal end 14 of shaft 2 spring 20 is provided with a rounded terminal element 18, for example a solidified droplet of brazing metal. Spring 16 is attached to shaft 2 at its proximal end and preferably also at an additional location, for example by means of a brazing or solder or adhesive connection. The core wire of the guide wire and thus shaft 2 preferably are made of Nitinol.

Although an embodiment of the invention having two bent or curved sections has been described above with reference to FIGS. 4 to 7, the guiding aid may comprise three or more bent or curved sections.

Claims

1. Guiding aid for an instrument to be advanced within a vascular system comprising a flexible shapeable shaft (2) comprising a first bent section (4) having a first curvature K_1, characterized by shaft (2) comprises at least one further bent section (6), with said bent sections (4, 6) of said shaft (2) having the same sign of curvature and being located substantially in the same plain (E).

2. Guiding aid as claimed in claim 1, characterized in that said shaft (2) comprises a single further or second bent section (6) having a second curvature K_2, which second bent section is located proximal to the first bent section (4).

3. Guiding aid as claimed in claim 2, characterized in that the radius of the first curvature K_1 of said first bent section (4) is smaller than the radius of the second curvature K_2 of said second bent section (6).

4. Guiding aid as claimed in anyone of claims 2 or 3, characterized in that said shaft (2) comprises a straight intermediate section (8) between said first bent section (4) and said second bent section (6).

5. Guiding aid as claimed in anyone of the preceding claims, characterized in that said shaft (2) comprises a straight end section (10) distal to the first bent section (4).

6. Guiding aid as claimed in claims 4 and 5, characterized in that the straight end section (10) and the straight intermediate section (8) include a first obtuse angle (α_1).

7. Guiding aid as claimed in claim 4 or in claims 4 and 5 or in claim 6, characterized in that said straight intermediate section (8) and the axis (12) of the instrument include a second obtuse angle (α_2).

8. Guiding aid as claimed in claim 6 or 7, characterized in that said first obtuse angle (α_1) and/or said second obtuse angle (α_2) are between 120° and 150° and preferably are about 135°.

9. Guiding aid as claimed in anyone of the preceding claims, characterized in that said bent sections (4, 6) are substantially in the shape of a circular arc.

10. Guiding aid as claimed in anyone of the preceding claims, characterized in that said shaft (2) is tapered towards its distal end (14).

11. Guiding aid as claimed in anyone of the preceding claims, characterized in that a helically wound spring (16, 20) is located around at least a part of said shaft (2).

12. Guiding aid as claimed in claim 11, characterized in that said helically wound spring (20) is provided at its distal end with a rounded terminal element (18).

13. Guiding aid as claimed in anyone of the preceding claims, characterized in that said shaft (2) is made of a material having superelastic characteristics.

14. Guiding aid as claimed in claim 13, characterized in that said shaft (2) is made of superelastic nitinol.

15. Guiding aid as claimed in anyone of the preceding claims, characterized in that radiopaque means (20) are provided in the region of said distal end (14) of said shaft (2).

16. Steerable guide wire comprising a guiding aid as claimed in anyone of claims 1 to 15.

17. Steerable pressure sensing wire comprising a guiding aid as claimed in anyone of claims 1 to 15.

18. Steerable catheter, in particular steerable balloon catheter, comprising a guiding aid as claimed in anyone of claims 1 to 15.

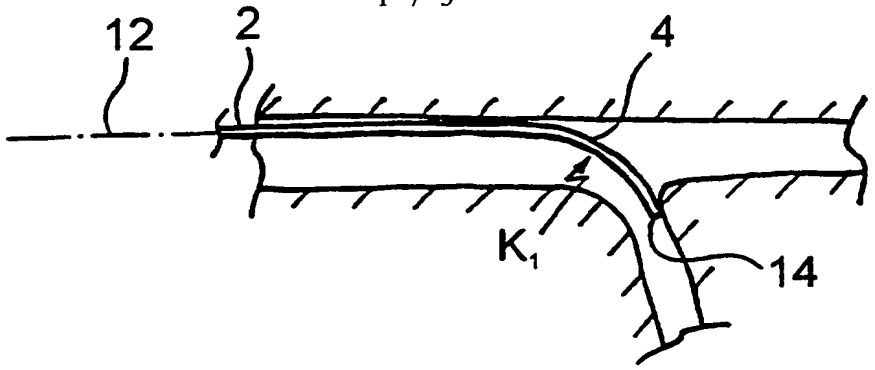


Fig. 1

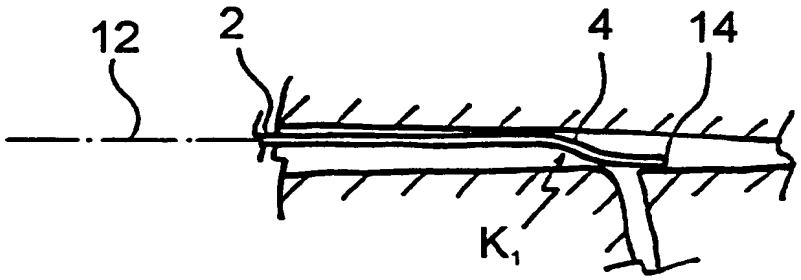


Fig. 2

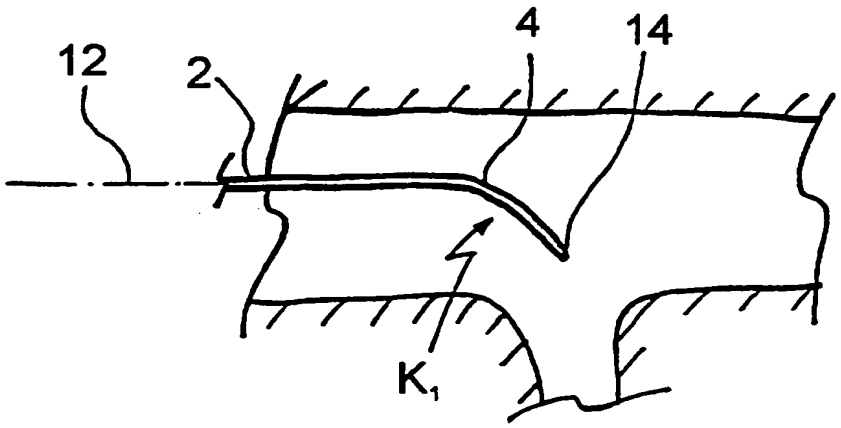


Fig. 3

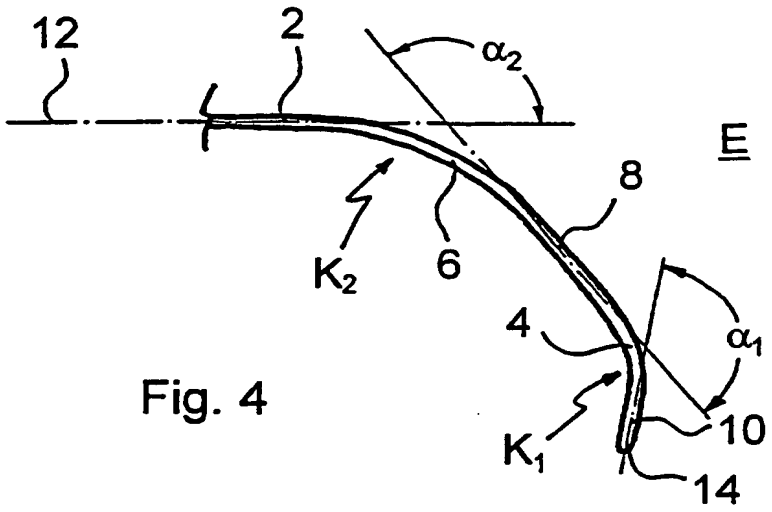


Fig. 4

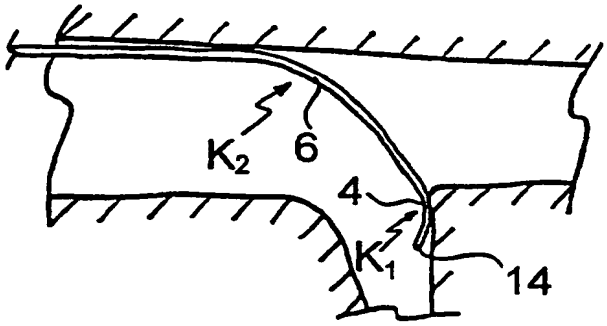


Fig. 5

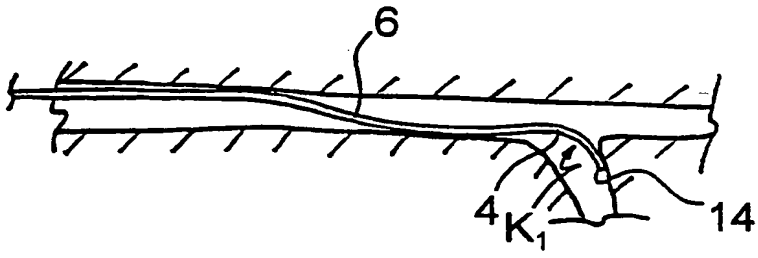


Fig. 6

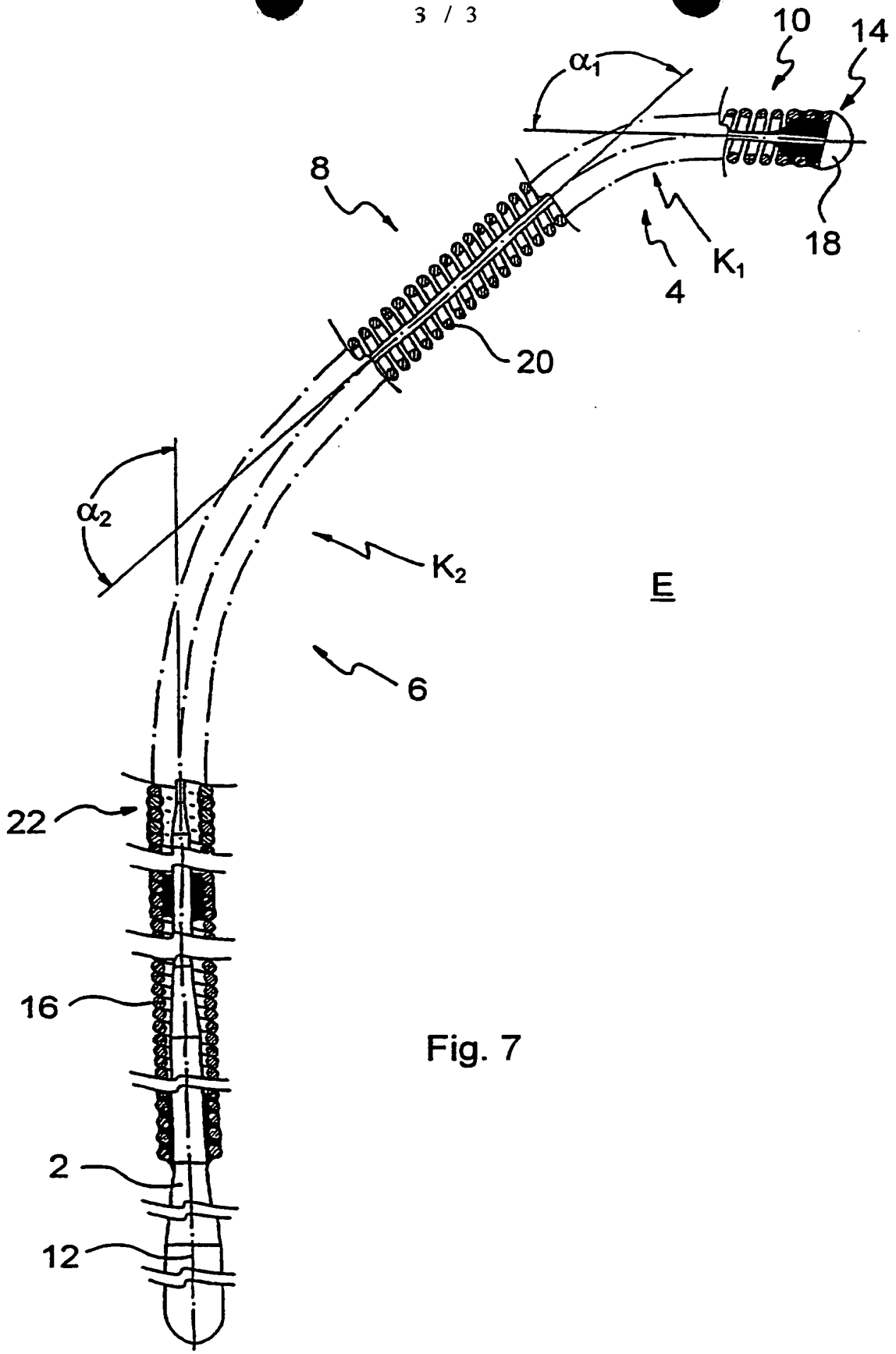


Fig. 7